

REMARKS

I. INTRODUCTION

The Examiner participated in a first telephone interview with Applicants on July 5, 2007 (the “First Interview”), in which independent claims 27 and 37 and U.S. Patent Application Publication No. 2002/0095197 filed by Lardo et al. (the “Lardo Publication”) and U.S. Patent No. 6,811,562 issued to Pless et al. (the “Pless Patent”) were discussed. Further, the rejection under 35 U.S.C. § 112 was also discussed in the First Interview. Additionally, the Examiner participated in subsequent interviews on October 4, 2007 and October 9, 2007. Applicants thank the Examiner for participating in each of the telephone interviews.

Claims 36, 38 and 52 have been amended to remove minor informalities therefrom. Claims 35 and 51 have been canceled without prejudice. Independent claims 27 and 37 have been amended to incorporate the subject matter of now-canceled claims 35 and 51. In addition, new claims 53-55 have been added above. Applicants respectfully assert that the amendments to claims 27, 36, 37, 38 and 52, as well as the addition of new claims 53-55 have not been made for any reason relating to patentability thereof, and comply with the requirements as set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. OBJECTIONS TO CLAIMS AND SPECIFICATION SHOULD BE WITHDRAWN

In the Final Office Action, the Examiner objected to claims 35, 36, 51 and 52 because of minor informalities associated with dependency therefrom. As the Examiner shall ascertain, claims 35 and 51 have been canceled without prejudice, and

claims 36 and 52 have been amended above to remove the minor informalities indicated by the Examiner in the Final Office Action. Accordingly, Applicants respectfully submit that the objection to the claims is now moot, and should therefore be withdrawn.

Further, in the Final Office Action, the Examiner objected to the Specification because it allegedly fails to provide proper antecedent basis for the claimed subject matter of independent claim 37 and the claims which depend therefrom. Examiner contends that the Specification of the present application allegedly “fails to disclose the arrangement for detecting or treating . . . where a location of the volume of the target area which receives the fluid is provided at a distance from a location of an introduction of the fluid to a portion of the subject.” See Final Office Action, dated June 13, 2007, ¶ 1. Applicants respectfully disagree.

Indeed, the Specification of the present application provides proper support for the recited subject matter. Referring to the originally-filed Specification of the present application, an exemplary embodiment is described therein in which, *inter alia*, a fluid delivery system can be used to inject a fluid into a vein of a subject and the fluid may be delivered to the target area of the subject via, e.g., a coronary artery. See Specification, para. [0015]. The target area has a volume associated with it and that volume has a location in the subject. The location of introduction, for example, a vein, may be located at a distance from the volume and the fluid may have to travel via, for example, a coronary artery. See Specification, para. [0015]. Therefore, the Specification provides abundant support for such recited subject matter. Accordingly,

Applicants respectfully submit that the objection to the Specification should therefore be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 112 ¶ 2 SHOULD BE WITHDRAWN

Claims 37-52 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite. Specifically, the Examiner believes that in claim 37, it is unclear what is being claimed by “a location of the volume of the target area,” because a volume allegedly is not considered to have a location. During the First Interview, it is believed that the Examiner confirmed that these terms are not indefinite. Indeed, volume is a measure of the amount of space something occupies in three dimensions and, therefore, has a location in a three dimensional space. Therefore, “the volume of the target area” also has a location in a three dimensional space. Accordingly, the rejection of claims 37-52 under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite should be withdrawn.

IV. REJECTIONS UNDER 35 U.S.C. §§ 102(b) AND 102(e) SHOULD BE WITHDRAWN

Claims 27-52 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by the Lardo Publication. Additionally, claims 27-52 stand rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by the Pless Patent. It is respectfully asserted that neither the Lardo Publication nor the Pless Patent disclose the subject matter recited in amended independent claims 27 and 37 of the above-referenced

application, and claims which depend therefrom, for at least the reasons provided in greater detail herein below.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, § 2131; *see also Lindman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Applicants' invention, as recited in amended independent claim 27, relates to an arrangement for detecting or treating cardiac abnormalities and cardiac inconsistencies, which comprises, *inter alia*:

a fluid delivery system structured to introduce a fluid to a target area of a heart of a subject, wherein a volume of the target area which receives the fluid is less than a volume of the heart, wherein the target area has a predetermined metabolism, and wherein the fluid is provided to be received only by those areas of the heart having a metabolism which is (i) greater than or equal to or (ii) less than or equal to the predetermined metabolism.

Amended independent claim 37 relates to another arrangement, which recites similar subject matter.

The Lardo Publication relates to methods and devices for treating and curing cardiac arrhythmias using photo-chemotherapy or photodynamic therapy. (See Lardo Publication, ¶ [0026]). The method includes administering a photosensitizing agent to a patient's cardiac tissue, from which abnormal signals causing arrhythmias arise and/or by normal tissues that assist in sustaining arrhythmias. (See *id.*, ¶¶ [0027-0028]). The agent may be administered in a variety of ways, including systemically, via an angioplasty catheter balloon, or by perfusing the agent directly into the coronary

arteries. (See *id.*, ¶¶ [0028-0032]). The photosensitizing agent may then be activated through a variety illumination methods. (See *id.*, ¶¶ [0027] and [0035]).

The Pless Patent relates to procedures and devices for treating cardiac tissue by forming lesions in the tissue using photodynamic therapy techniques. (See Pless Patent, column 1, lines 7-9). The Pless Patent describes a means of detecting cardiac arrhythmias by using an electrocardiogram (EKG) to detect the electrical activity within the heart. (See *id.*, column 2, lines 47-60). Further, the Pless Patent describes a method that includes introduction of a photodynamic drug through, for example, an intravenous injection or local administration. (See *id.*, column 9, lines 42-45). Additionally, the Pless Patent describes use of a light source to focus energy on a specific region on the heart to excite the photodynamic drug once it has been administered. (See *id.*, column 1, lines 19-41 and 47-59).

In clear contrast to the Applicants' claimed invention, the Lardo Publication and the Pless Patent do not disclose an arrangement in which, *inter alia*, a fluid delivery system structured to introduce a fluid to a target area of a heart of a subject, wherein **the target area has a predetermined metabolism**, and wherein **the liquid is provided to be received only by those areas of the heart having a metabolism which is (i) greater than or equal to or (ii) less than or equal to the predetermined metabolism**, as recited in amended independent claims 27 and 28.

Clearly, neither the Lardo Publication nor the Pless Patent recite each and every element of amended independent claims 27 and 37, as required for a rejection under 35 U.S.C. § 102. Indeed, the Examiner does not point to any section of the Lardo Publication or the Pless Patent as allegedly disclosing **a target area having a**

predetermined metabolism and a liquid that is provided to be received only by those areas of the heart having a metabolism which is (i) greater than or equal to or (ii) less than or equal to the predetermined metabolism. According to the Examiner, however, both the Lardo Publication and the Pless Patent allegedly “disclose the structural limitations, and, therefore, are seen as being capable of performing the intended use which is recited in the claims.” See Final Office Action, dated June 13, 2007, ¶ 8 (apparently with reference to now cancelled claims 35 and 51 the subject matter of which have been now incorporated into independent claims 27 and 37). Contrary to the Examiner’s apparent contentions, it cannot be assumed (as well as not disclosed) that the structures described in the Pless Patent and the Lardo Publication are structured to introduce a fluid to a target area, in which the target area has a predetermined metabolism and the liquid is provided to be received only by those areas of the heart having a metabolism which is (i) greater than or equal to or (ii) less than or equal to the predetermined metabolism, as recited in amended independent claims 27 and 37. Neither the Pless Patent nor the Lardo application disclose such limitations and the Examiner does not suggest that they do. Accordingly, it is respectfully asserted that the Lardo Publication and the Pless Patent do not disclose the recitation of amended independent claims 27 and 37.

Therefore, for at least the reasons as presented herein above, Applicants respectfully request the 35 U.S.C. §§ 102(b) and 102(e) rejections of claims 27-36 and 37-52, respectively, be withdrawn.

V. CONCLUSION

In light of the foregoing, Applicants respectfully submit that pending claims 27-34, 36-50 and 52-55 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited. If any issues remain outstanding, the Examiner is invited to contact the undersigned via the telephone number provided below.

Respectfully submitted,

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